IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No.	:	09/617,868	Confirmation No. 8293
Applicant	:	Thomas J. Shaw	
Filed	:	July 17, 2000	
TC/Art Unit	:	3767	
Examiner	:	MacNeill, Elizabeth R.	
For	:	RETRACTABLE SYRINGE ASSEMBLY DESIGNED FOR ONE USE	
Docket No.	:	575329.77432 (formerly 75329.77432)	

Via Electronic Filing

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

DECLARATION OF THOMAS J. SHAW
UNDER 37 C.F.R. §1.132

I, Thomas J. Shaw, the Applicant and named inventor of the subject matter disclosed and claimed in the above-referenced patent application, hereby declare as follows:

1. I have read and am generally familiar with U.S. Patent Application No. 09/617,868 (the '868 application), filed July 17, 2000, which has now been pending for more than six (6) years.

2. The '868 application is related to and claims priority from U.S. Patent Nos. 5,578,011 (issued November 26, 1996), 5,632,733 (issued May 27, 1997) and 6,090,077 (issued July 18, 2000). I am the inventor named on each of those

prior patents and on 44 related foreign counterpart patents that have issued throughout the world. I am also the inventor named on U.S. 5,385,551 (issued January 31, 1995), another syringe patent based upon an earlier patent application filed in 1993.

3. The initial development of the inventions disclosed and claimed in the '868 application and in the other patents identified in paragraph 2 was initially funded by two Small Business Innovation Research (SBIR) grants received from the National Institute on Drug Abuse, a division of the National Institutes of Health (NIH).

4. The safety syringe technology embodied in the inventions disclosed in the '868 application and in the other related patents identified in paragraph 2 has been commercialized by Retractable Technologies, Inc. (RTI), a publicly owned corporation headquartered in Little Elm, Texas, in syringes that are marketed under the federally registered trademark "VanishPoint."

5. RTI's VanishPoint® syringes are manufactured in plants located in Little Elm, Texas and in China, and are being offered for sale in countries throughout the world. Clinical acceptance of the VanishPoint® syringes has been demonstrated by the placement of approximately four million units in U.S. governmental facilities and almost 400 million units in the global marketplace.

6. RTI is the only U.S. manufacturer of syringes that has supplied retractable syringes for use in the President's $15 billion AIDS relief program for African nations.

7. In 2003, Frost & Sullivan, an international business research and consulting firm, named RTI as the recipient of its Product Quality Leadership Award for developing, manufacturing and marketing the VanishPoint® line of automated retraction safety needle devices. Frost & Sullivan found that the VanishPoint®

product line represented a major improvement over other retractable syringes then on the market. Amit Bohora, a Frost & Sullivan industry analyst, stated, "VanishPoint® devices are clearly the gold standard in retractable syringes."

8. In September 2003 an "Evaluation of Needlestick-Prevention Devices" ("Evaluation") focusing on disposable syringes and injection needles was published by ECRI in Vol. 32, No. 9, of *HEALTH DEVICES*. ECRI is a nonprofit agency formerly known as the Emergency Care Research Institute. Articles published by ECRI are subject to peer review, and ECRI prides itself in being impartial toward all ethical medical device companies and practices. ECRI prohibits manufacturers from using or referring to product ratings or reports in advertising or promotional materials. A copy of the Evaluation is not attached to this Declaration because duplication of each page of the Evaluation by any means for any purpose is prohibited.

9. In the Evaluation, ECRI considered 14 different disposable needle and injection needle products, collectively referred to as "needlestick prevention devices" (NPDs), then being offered commercially by nine different manufacturers. The 14 products were further subdivided into "disposable protective syringes" and "needle guards." Of the 14 products, eight were classified as "disposable protective syringes." The eight disposable protective syringes were subclassified into one of the following four ratings categories: "Preferred," "Acceptable," "Not Recommended" or "Unacceptable." Of the eight disposable protective syringes, three were rated "Preferred," one was rated "Acceptable" and three were rated "Not Recommended."

10. RTI's VanishPoint® syringe was one of the three rated "Preferred." Another of the three rated "Preferred" was manufactured by a competitor of RTI that was sued for patent infringement by RTI and is no longer manufacturing the syringes.

11. In 2005, I was informed by Zhuoping Huo, MD, MPH, Associate Director of the Chinese Center for Disease Control and Prevention, that the China CDC had undertaken a study of the commercially available retractable syringe technologies and had identified RTI as its manufacturer of choice to license technology to a Chinese entity to manufacture VanishPoint® syringes for use in immunization programs in China.

12. Another article titled "Syringe Safety Controls" by Susannah Chance, Department of Biomedical Engineering, Texas A&M University, was more recently published in the Journal of Clinical Engineering (July/September 2006). A copy of the article is attached as Exhibit A to this Declaration. The article addresses critical questions regarding the high accidental needlestick rate, especially for healthcare workers and identifies factors to be considered in designing an effective safety syringe. At p. 154, the article recognizes the VanishPoint® syringe manufactured and marketed by RTI as an example of the most effective type of needle protection device.

13. I have read and am generally familiar with the November 20, 2006, office action that rejects all pending claims of the '868 application as being anticipated either by U.S. 5,084,018 to Tsao or by U.S. 5,211,629 to Pressly et al. I have also read and am generally familiar with the Tsao '018 and Pressly et al. '629 patents.

14. I have read and am generally familiar with the Amendment and Response filed concurrently with this Declaration, including the claims as presented in it, and actively participated in drafting and revising those claims. I am the sole inventor of the subject matter recited in each of the amended claims, and have executed a Supplemental Declaration of Inventor that is being filed concurrently with the Amendment and Response, and with this Declaration.

15. Many prior inventors have filed patent applications, and many patent

applications have issued, for syringes ostensibly having retractable needles. Some of the disclosed devices contain structures that cannot even be manufactured as shown, or will not function as described. Other previously disclosed devices are not susceptible to being manufactured reliably at high speed so as to achieve production rates commensurate with an acceptable price for the finished product. Still others leak when subjected to injection pressure and do not satisfactorily seal the medication inside the syringe prior to injection, sometimes spraying expensive medications out through the nose of the syringe. Still others cannot retract a needle until it is withdrawn from a patient. Still others cause a patient's blood and blood-borne pathogens to be expelled forwardly through the nose of the syringe upon retraction. Still others require too great a thumb force to initiate retraction. Still others will not reliably prevent premature retraction during transportation and handling, or when inserted into a medicine vial. Still others cause pain to a patient because the needle advances forwardly before it is forced back inside the barrel or retraction cavity during retraction. Still others malfunction when subjected to temperature variations prior to use. Still others cannot be used to administer an injection and retract the needle using a single hand. Still others have unacceptable "dead space."

16. In an effort to comply with my duty of disclosure to the United States Patent Office, my attorneys have previously filed on behalf of myself and RTI an Information Disclosure Statement and four Supplemental Information Disclosure Statements to make of record information known to me or received during the prosecution of other U.S. or foreign patent applications. A Fifth Supplemental Information Disclosure Statement is being filed concurrently with this response.

17. I have personally spent more than 15 years studying safety syringes and developing and refining the VanishPoint® syringes. After more than a decade of research, development and actual use by clinicians, RTI has succeeded

under my leadership in producing and demonstrating the reliability and efficacy of the VanishPoint® syringes that I invented.

18. Examiner has rejected many claims of the '868 application as being anticipated by U.S. 5,084,018 to Tsao, and many other claims as being anticipated by U.S. 5,211,629 to Pressly et al. After considering Examiner's rejections, the cited references, and other prior art of which I am aware, I have worked together with my attorneys to amend further the pending claims of the '868 application to better define and patentably distinguish the syringe I invented over those syringes that have been disclosed by Tsao, Pressly et al., and others.

19. I believe that an invention embodying the elements recited in combination in each respective pending claim as amended in the Amendment and Response filed concurrently with this Declaration have not been disclosed in any prior art reference of which I am aware. Although no claims are presently rejected based upon obviousness, I further believe that the invention as recited in each claim presented in the Amendment and Response would not have been obvious to a person of ordinary skill in the art having knowledge of the prior art at the time my disclosures of the claimed subject matter were made.

20. As noted, for example, in the article attached as Exhibit A to this Declaration, the societal need for safe and reliable syringes is enormous. The societal cost of treating those infected with blood-borne pathogens contracted through the use of unsafe syringes is likewise enormous. Although many, many so-called "safety syringes" have been invented on paper, very few therapeutically acceptable safety syringes have ever even "made it to market," and fewer still have been recognized and acknowledged by clinicians as representing a safe and effective product that constitutes a significant advancement in the state of the art. I submit that the safety syringes as recited in the amended claims of the '868 application presented in the Amendment and Response filed

concurrently with this Declaration are both novel and nonobvious, and are entitled to patent protection.

21. Because the '868 patent application claims subject matter developed in part with U.S. governmental funding, I understand that the U.S. government may have some march-in rights as provided under the patent statutes to any patent that may issue on this application, providing further benefit to the people of the United States as to any patent that may issue on the amended claims.

22. All statements made herein of my own knowledge are true, and all statements made on information and belief are believed to be true.

I understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. §1001), and may jeopardize the validity of the application or any patent issuing thereon.

Thomas J. Shaw

Date: 2/23/07